NOV 18 2011

## Exhibit #2 510(k) Summary

This 510(k) Summary is prepared per the requirements of 21 CFR 807.92(k).

The assigned 510(k) Number is: K102833

1. Date of Preparation: 31 OCT 2011

2. Sponsor Information

Foshan Nanhai Bai He Medical Technology Co., LTD
*Establishment Registration Number: 3006621386*
No. 5, Taoyuan West Road, Nanhai Software Tech. Park,
Foshan Guangdong, 528225, China

Contact Person: Mr. Baoyou Ge, Position: Management Representative
Tel: +86-757-81207300|Fax: +86-757-81207311

3. Submission Correspondent

Ms. Diana Hong, Mr. Lee Fu
Mid-Link Consulting Co., Ltd
P.O. Box 237-023, Shanghai, 200237, China
Tel: +86-21-22815850|Fax: 240-238-7587|Email: info@mid-link.net

4. Proposed Device Identification

Trade Name: Disposable Hemodialysis Access Catheter Set;
Classification Name: Catheter, Hemodialysis, Non-implanted;
Regulation Number: 21 CFR 876.5540
Review Panel: Gastroenterology/Urology

Intended Use:

Disposable Hemodialysis Access Catheter Sets, including Single-lumen and Dual-lumen, are intended to attain long or short term (less than 30 days) vascular access for hemodialysis via the internal jugular, subclavian or femoral vein.

Device Description:

Disposable Hemodialysis Access Catheter Sets, including Single-lumen and Dual-lumen, are intended to attain long or short term (less than 30 days) vascular access for hemodialysis via the

internal jugular, subclavian or femoral vein. It consists of a catheter, a puncture needle, a guide wire and a dilator. The set is provided EO sterilized.

5. Test Conclusion

Laboratory testing was conducted to validate and verify that Disposable Hemodialysis Access Catheter Set met all design specifications and was substantially equivalent to the predicate device. These tests include:

a. Biocompatibility Tests per ISO 10993-1:2009 were performed to evaluate the biocompatibility of the materials of the proposed device. The test results were determined to be acceptable;
b. Performance Tests per ISO 10555-1:1995/AMD.1:1999/AMD.2:2004(E) and ISO 10555-3:1996/AMD.1:1999 were performed to evaluate the physical performance of the proposed device, including surfaces, dimensions, mechanical strength, leakage, flow rate and fatigue. The test results demonstrated that the proposed devices comply with the performance standards;
c. Recirculation and Repeated clamp tests;
d. Sterilization Validation Study per ISO 11135-1:2006 were performed. The results demonstrated that the sterilization method and cycle of the proposed device could reach SAL of $10^{-6}$, and the sterilant residual was acceptable;
e. Package Integrity Tests, including seal strength, internal pressure and dye penetration, were performed to evaluate the package integrity of the proposed device to demonstrate that the immediate package could maintain the sterility during its shelf life.

6. Substantially Equivalent

Predicate Device 1: Niagara®, Niagara® Slim-Cath®, Brevia® Dual Lumen Catheters
510(k) Number: K090102

Predicate Device 2: Joline D-Line Catheter STfamily of catheters in kits consisting of
Dual Lumen Short Term Hemodialysis Catheter
Extra Flow (EF) Short Term Hemodialysis Catheter
510(k) Number: K063355

**SE Claim: the proposed device, Disposable Hemodialysis Access Catheter Set, is claimed to be substantially equivalent (SE) to the predicate devices.**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Foshan Nanhai Bai He Medical Technology Co., LTD
% Ms. Diana Hong
General Manager
MID-LINK Consulting Co., Ltd
P.O. Box 237-023
SHANGHAI
CHINA 200237

NOV 18 2011

Re: K102833
Trade/Device Name: Disposable Hemodialysis Access Catheter Set
Regulation Number: 21 CFR§ 876.5540
Regulation Name: Blood access device and accessories
Regulatory Class: II
Product Code: MPB
Dated: October 31, 2011
Received: November 14, 2011

Dear Ms. Hong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Exhibit #1 Indication for Use statement

510(k) Number: K102833
Device Name:Disposable Hemodialysis Access Catheter Set

Indicationfor Use:

Disposable Hemodialysis Access Catheter Sets, including single lumen and dual lumen, are indicated for use in attaining short-term (less than 30 days) vascular access for hemodialysis via the internal jugular, subclavian or femoral vein.

☒PRESCRIPTION USE
(Part 21 CFR 801 Subpart D)

☐OVER-THE-COUNTER USE
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K102833